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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/690,384      | 10/20/2003  | Curtis Wright IV     | 6750-237-99         | 2381             |

20583 7590 11/03/2006

JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER

MERCIER, MELISSA S

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1615

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/690,384

Applicant(s)

WRIGHT, CURTIS

Examiner

Melissa S. Mercier

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 26-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Receipt of Applicants remarks, filed on October 6, 2006, electing Claim 25 for examination is acknowledged.

Claim 25 is rejected.

### *Information Disclosure Statement*

It appears that the Information Disclosure Statement received on October 20, 2003 is a copy of the Information Disclosure Statement of Application 09/714,604, of which the instant application is a continuation of. In order to clarify the record, it is requested that applicant submit a new copy of the Information Disclosure Statement.

According to MPEP:

\*A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

\*If resubmitting a listing of the information, applicant should submit a new listing that complies with the format requirements in 37 CFR 1.98(a)(1). Applicants are strongly discouraged from submitting a list that includes copies of PTO/SB/08 (PTO-1449) or PTO-892 forms from other applications. **A completed PTO/SB/08 or PTO-1449 form from another application may already have initials of an examiner and the application number of another application. This information will likely confuse the record.** Furthermore, when the spaces provided on the form have initials of an examiner, there are no spaces available next to the documents listed for the examiner of the subsequent application to provide his or her initials, and the previously relevant initials may be erroneously construed as being applied for the current application.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pagedas (US Patent 6,221,384) in view of Benecke et al. (US Patent 5,008,110).

Pagedas teaches "a transdermal segmented dosage unit for administering a dosage of a pharmaceutical to the skin of a patient. The dosage unit includes a backing layer which is non-permeable with respect to a pharmaceutical to be administered by the dosage unit, a membranous layer that is permeable to the pharmaceutical, a biologically acceptable adhesive, an impermeable coating means for dividing and severing the dosage unit into pre-selected segmental areas corresponding to fractional dosages of pharmaceutical. The fractional dosages may be administered in any pre-selected combination" (abstract).

Pagedas's transdermal dosage unit, discloses, "a series of perforations or alternately, scoring lines, with purpose to divide the dosage unit into a series of dose specific segments. Thus the dosage unit patch may be used in its entirety for the full

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dosage, or in the alternative, may be separated along perforate or scored lines to reduce the dosage received by a predetermined amount" (column 1, lines 50-55).

Applicant's attention is directed to Pagedas's drawings for a clear representation of the dosage units.

Pagedas does not teach the pharmaceutical agent to be buprenorphine.

Benecke teaches a transdermal device for the topical administration of buprenorphine.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the transdermal segmented dosage units taught by Pagedas with the agent taught by Benecke in order to provide a method of delivering buprenorphine to a patient and "if the patient is unable to tolerate the full dosage, may use any fractional dosage obtainable by separating out the appropriate fractional dose from the total dosage patch. The fractional doses unused after separation may be used at a later time, thus reducing waste" (Pagedas, column 1, lines 61-65).

Applicant would have a reasonable expectation of success since both references teach the use of transdermal patches for administering a drug to a patient.

### ***Conclusion***

No claims are allowable.

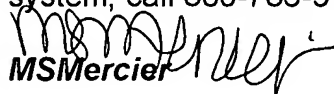
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liedtke (US Patent 5,686,112).

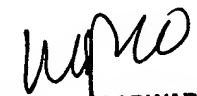
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MSMercier

  
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SUPERVISORY PATENT EXAMINER  
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